# SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

### FORM 6-K

REPORT OF FOREIGN PRIVATE ISSUER PURSUANT TO RULE 13a-16 OR 15d-16 OF THE SECURITIES EXCHANGE ACT OF 1934

For the month of September 2011

# **BioLineRx** Ltd.

(Translation of Registrant's name into English)

### P.O. Box 45158 19 Hartum Street Jerusalem 91450, Israel

(Address of Principal Executive Offices)

Indicate by check mark whether the registrant files or will file annual reports under cover of Form 20-F or Form 40-F:

### Form 20-F 🗹 Form 40-F o

Indicate by check mark whether the registrant by furnishing the information contained in this form is also thereby furnishing the information to the Commission pursuant to Rule 12g3-2(b) under the Securities Exchange Act of 1934:

Yes o	No 🗹
-------	------

On September 13, 2011, the Registrant will issue the press release which is filed as Exhibit 1 to this Report on Form 6-K. This report on Form 6-K is being incorporated by reference into all effective registration statements filed by us under the Securities Act of 1933.

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

## BioLineRx Ltd.

By: /s/ Philip Serlin

Philip Serlin Chief Financial and Operating Officer

Dated: September 12, 2011



For immediate release

# BioLineRx Announces Positive Preliminary Results from Phase I Clinical Trial of BL-1021 for Neuropathic Pain

#### - Results show the drug is safe and well tolerated -

Jerusalem, September 13, 2011 - BioLineRx (NASDAQ: BLRX) (TASE: BLRX) announced today the last visit of the last subject and preliminary results of the Phase Ia study of BL-1021, an orally available small molecule for neuropathic pain. Study results demonstrated that a single administration of BL-1021 was safe and well tolerated. In addition, preliminary modeling of the pharmacokinetic data collected in this trial predicts that a once daily administration of BL-1021 at the dose levels assessed in the trial will enable reaching effective doses in patients. Final results are expected to be announced in the fourth quarter of 2011.

The trial was a first-in-human, double-blind, placebo-controlled study performed at the Hadassah Clinical Research Center, Jerusalem, Israel. The study aimed at assessing the safety, tolerability and pharmacokinetics (PK) of a single administration of BL-1021 at doses between 10 mg and 80 mg.

Dr. Kinneret Savitsky, BioLineRx's CEO, stated, "this Phase I trial has demonstrated the safety and tolerability of BL-1021 and we believe it has the potential to provide improved efficacy without the side effects associated with many existing medications. We are also encouraged by the favorable pharmacokinetic profile of BL-1021 and anticipate that the final results and analysis will confirm that BL-1021 has the competitive advantage of a once daily administration. This trial is an important milestone towards the commercialization of BL-1021."

#### About BL-1021

BL-1021 is an orally available small molecule for the treatment of neuropathic pain that was designed to share the activities of anti-neuropathic drugs without their common adverse effects. BL-1021's efficacy has been demonstrated in various animal models of neuropathic pain. Pre-clinical data demonstrate that BL-1021 has a lowered propensity for sedation, low cardiac toxicity and improved efficacy compared with other anti-pain medications.

#### **About Neuropathic Pain**

Neuropathic pain is a complex, chronic state of pain that results from dysfunctional or injured nerve fibers. Neuropathic pain is associated with various conditions, including shingles, diabetes and cancer and is reported to affect 1% to 3% of the population. Patients describe the symptoms as burning, stabbing, electric shock or itching sensations, which can cause extreme discomfort for extended periods of time. A variety of medications are used to treat neuropathic pain, including antidepressants and anti-seizure medicines. However, these medications have significant side effects and are not always effective. In 2009 the neuropathic pain market was estimated to be \$2.4 billion in the seven major markets (US, Japan, France, Germany, Italy, Spain and the UK), and it is projected to grow to \$4.1 billion in 2018.

### About BioLineRx

BioLineRx Ltd. is a publicly-traded biopharmaceutical development company. BioLineRx is dedicated to building a portfolio of products for unmet medical needs or with advantages over currently available therapies. BioLineRx's current portfolio consists of five clinical stage candidates: BL-1020 for schizophrenia is in Phase II/III clinical trials; BL-1040 for treatment of patients following a myocardial infarction has completed a Phase I/II study and has been out-licensed to Ikaria Inc. for a total deal value of \$282.5 million, in addition to sales royalties; BL-5010 for non-surgical removal of skin lesions has completed a Phase I/II study; BL-1021 for neuropathic pain is in Phase I trials; and BL-7040 for treating Inflammatory Bowel Disease (IBD) has completed Phase I. In addition, BioLineRx has nine products in various pre-clinical development stages for a variety of indications, including central nervous system diseases, oncology, infectious diseases, cardiovascular and autoimmune diseases.

BioLineRx's business model is based on acquiring molecules mainly from biotechnological incubators and academic institutions. The Company performs feasibility assessment studies and development through pre-clinical and clinical stages, with partial funding from the Israeli Government's Office of the Chief Scientist (OCS). The final stage includes partnering with medium and large pharmaceutical companies for advanced clinical development (Phase III) and commercialization. For more information on BioLineRx, please visit <u>www.biolinerx.com</u>.

The estimates and judgments with respect to the projects included in this release are considered forward-looking statements, which involve certain risks and uncertainties, and are based on information available to the Company at the time of this release. Such estimates may not be realized or may be only partially realized, due to the significant uncertainty characterizing research and development activities in general, particularly those of drug development, including changes in regulation or uncertainty relating to the application of regulation, unexpected delays in obtaining regulatory approval, unexpected delays in patient recruitment for clinical trials, unexpected delays in other clinical trial preparatory activities, inefficiencies, inability to manufacture, toxicity, a high level of risk/reward in comparison to current treatments available, as well as new information regarding intellectual property rights which may affect the economic viability of continued product development. The Company assumes no responsibility for updating forward-looking statements made herein or otherwise.

### Contacts:

Garth Russell / Todd Fromer KCSA Strategic Communications 1 212-896-1250 / 1 212-896-1250 grussell@kcsa.com / tfromer@kcsa.com

Tsipi Haitovsky Public Relations +972-3-6240871 <u>tsipih@netvision.net.il</u>

2